REMARKS

Claims 48-60 and 64-68 are pending in the Application. Claims 48-52, 56, and 66-67 have been amended. Claims 62-63 have been cancelled without prejudice. In the Final Office Action, claims 48-55 were objected to because claim 48 contained an obvious typographical error. Amended claim 48 corrects this error.

Turning now to the substantive rejections, claims 48-54, 56-58, 60, and 62-67 stand rejected as being anticipated under § 102(e) as being anticipated by U.S. Patent No. 6,679,890 (Marguilies et al.). Claims 48-60 and 62-67 were further rejected as being unpatentable over Marguilies et al. in view of U.S. Patent No. 6,248,110 (Reiley et al.). Applicants have made a number of clarifying amendments to even more succinctly claim the delivery method. Applicants submit that the claimed method, as represented by the current set of claims, is patentable over the cited art.

The primary Marguilies et al. reference discloses a method and device for the augmentation of the femoral neck. A hole is first drilled into the femoral neck and the hole is filled with uncured cement. An open-ended tube (i.e., implant) having openings at the ends and through its wall is then inserted into the hole and attached to the bone. An injection tube is provided to inject cement into the surrounding cancellous bone. The injection tube is described as being dimensioned (i.e., outer diameter) to provide a tight but sliding fit within the implant. Col. 4, lines 55-58. The space between the outer dimensions of the injection tube and the internal surface of the implant are large enough such that air escapes during cement injection but small enough such that cement does not flow backward through this annular space. Col. 6, lines 4-13. The only sealing aspect disclosed

in Marguilies et al. relates to the tight, sliding fit between the exterior surface of the injection tube and the inner surface of the implant – there is no separate sealing member.

In the Final Office Action (page 7, top paragraph), the position is taken that Marguilies et al. discloses an attached sealing member. The cited portion of Marguilies et al., however, does not disclose any separately attached sealing member. Rather, Col. 9, lines 27-31 states:

> *It is presumed that implants would, in time, be provided by a manufacturer in a kit also including a properly mating injection tube that assures a pressurizing sliding seal. Various lengths, diameters, cross-sections, materials, etc., would be available in a kit of elements.*

This portion of Marguilies et al. merely discloses that a kit is contemplated that would include both the (1) implant and (2) a properly mating injection tube that is sized to ensure that the sliding seal is properly formed when inserted into the implant. This passage of Marguilies et al. does not disclose or otherwise suggest any separate sealing member structure. As explained above, the only sealing aspect of the Marguilies et al. device is the tight, sliding fit formed between the exterior surface of the injection tube and the interior surface of the implant.

The Final Office action ignores the importance of this separate sealing member that is part of the plunger. In particular, the sealing member may be moved to selectively perfuse implant material out either the longitudinal opening in the cannula or through transverse openings located in the cannula body. For example, during typical use, the sealing member is located distal to the longitudinal opening in the cannula and is distal (i.e., separate) from the cannula body. This first configuration (illustrated in FIGS. 2A and 8A) permits perfusion of implant material out the longitudinal opening. The sealing member is

moved proximally to then bring the sealing member within the cannula body and proximal with respect to the longitudinal opening but distal with respect to the transverse opening. In this configuration, a seal is formed between the sealing member and the cannula body such that injected sealing material will perfuse via the transverse opening *but not the longitudinal opening*. Claims 48 and 66 have been amended to more particularly recite this claimed aspect. In addition, clarifying amendments to dependent claims 50, 51, and 52 have been made in light of the amendments to independent claim 48.

Amended claim 48, for instance, more particularly recites the longitudinal and transverse openings and more clearly states that the first position of the sealing member places the same distal with respect to the first longitudinal opening and distal with respect to the cannula (e.g., it projects from the distal end of the cannula body). In this position, implant material can perfuse out the distal longitudinal opening of the cannula body. Claim 48 has also been amended to state that the second position of the sealing member is located within the cannula body and proximal with respect to the longitudinal opening but distal with respect to the transverse opening. In this configuration, implant material may perfuse out the transverse opening *but not the longitudinal opening* because of the seal formed by the sealing member located within the cannula body. Claim 66 includes a similar clarifying amendment.

Marguilies et al. does not disclose a sealing member that can be positioned within the cannula body that enables perfusion through transverse openings but not the longitudinal opening. In the device of Marguilies et al. implant material is extruded through the end of the implant (2) *and* through the openings (60) contained in the implant. There is no sealing member disclosed that can isolate extruded material from flowing through the

hole (23) in the end of the implant (2). For at least this reason, claims 48-55 and 66-68 are patentable over Marguilies et al. The secondary Reiley et al. reference was only cited for the proposition that it was known prior to Applicants' invention to delivery an implant material through a cannula. As stated previously, Applicants do not dispute this aspect of Reiley et al. Instead, Applicants' submit that Reiley et al. provides no teaching or suggestion of the method of delivering an implant material as disclosed and claimed in the present application, and does not supply any of the above-discussed missing claim limitations.

Applicants have amended independent claim 56 to recite the aspect that the cannula body includes a plurality of notches disposed in the wall of the cannula body. In addition, claim 56 has been amended to recite the aspect that the proximal end is separated from the distal end of the cannula body at one of the plurality of notches. A related amendment has been made to dependent claim 49. These claimed aspects may be found, for instance, in the specification at ¶ [0035]. Marguilies et al. does not disclose any separation process other than the aspect of "trimming" the distal end of any excess or exposed portion of the implant. Col. 5, lines 64-67. Regardless of whether "trimming" is separation, Marguilies et al. fails to disclose or suggest the claimed feature of separating proximal and distal ends at one of the plurality of notches formed in the cannula body.

Dependent claim 67 has been amended to recite the aspect wherein separation of a proximal portion of the cannula body from a distal portion is accomplished by unscrewing the distal portion from the proximal portion via a threaded junction disposed on the cannula body. Support for this aspect may be found in the specification at ¶ [0035]. Marguilies et al. does not disclose any threaded junction located in the cannula body that is unscrewed

to separate the same into proximal and distal portions. Applicants have also added new dependent claim 68 which recites the claimed aspect of separating the cannula body into proximal and distal portions at a connective sleeve interposed between the proximal and distal portions. An external force is applied to separate the two portions. Support for this aspect may be found in the specification at ¶ [0035].

Applicants submit that the amendments made herein further clarify certain salient claimed features of Applicants' claimed method and do not require an additional search. The amendments and remarks presented herein are believed to fully address the outstanding issues set forth in the Final Office Action and place the claims in condition for allowance. If the Examiner has any questions or comments regarding this amendment, the Examiner is respectfully requested to contact the undersigned at (949) 724-1849 (x. 104).

Respectfully submitted,

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